

REMARKS/ARGUMENTS

The foregoing amendments and these remarks are responsive to the non-final Office Action mailed January 27, 2006. By this Amendment, Claim 1 has been amended. No claims have been added or cancelled. Additionally, the Specification has been amended to more accurately describe the invention.

In the Office Action, Claims 1-25 were rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich, U.S. Pat. No. 5,409,488 ("Ulrich"); Claims 1-4, 6 and 15-25 were rejected under 35 U.S.C. 102(b) as being anticipated by Fournet-Fayard, U.S. Pat. No. 5,486,174 ("Fournet"); Claims 1, 7 & 8 were rejected under 35 U.S.C. 102(b) as being anticipated by Errico, U.S. Pat. No. 5,554,157 ("Errico"); and Claims 1& 12-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Urbanski U.S. Pat. No. 5,634,925 ("Urbanski"). Applicant submits that Applicant's claims are patentable overall of the references of record.

It may be helpful initially to reiterate certain features and aspects of the invention. A review of the particular problems involved in facet joint repair/reconstruction might also be helpful. Each vertebra in the human spine has two sets of joints which interact with adjacent upper and lower joints. These joints are known as the facet joints, and are otherwise known as the zygapophyseal or apophyseal joints. Two joints are formed on each lateral side of the vertebra. The superior articular facet faces upward and the inferior articular facet faces downward, such that the superior articular facet of a lower vertebrae abuts the inferior articular facet of an adjacent upper vertebrae. The facet joints are located on the posterior of the spine adjacent the pedicle, lamina, and transverse process. The facet joints generally are hinge-like and allow limited flexion, extension, and twisting motion, while preventing excessive motion which could damage the spinal chord. Spinal reconstructive or treatment procedures require the

removal of the facet joint and ligament structures. The joint and ligament must then be reconstructed artificially. The challenge in such procedures is to provide strength and stability, while as closely resembling the flexibility and range of motion of the natural facet joint as possible. Known artificial facet joints fail to provide the rigidity that is necessary to support the spine while permitting the flexibility to resemble the facet joint. The references cited would fail to solve this complex problem.

The cited references are all directed to fixation of the spine. Ulrich is directed to a spondylodesis implant ("When such implant is affixed with each of its connection pieces to one of three successive vertebrae, by rotating the threaded spindles, the two outer vertebrae can be independently set and fixated with respect to the middle vertebrae", Col 1, lines 63-67; "An implant for fixation and correction of the relative position of vertebrae", Claim 1, line 1).

Fournet similarly does not disclose or suggest structure suitable for a facet replacement. Fournet is directed to a fastener for lumbosacral osteosynthesis. The disc 5j, although angularly movable for purposes of installation, is fixed in place during use ("Then, the surgeon locks the disk (5j) inside the bore (5e) by means of screw (5i)", Col. 3, lines 15-16). Thus, there is no pivoting of the rod relative to the screw.

Errico discloses a rod securing polyaxial locking screw and coupling element assembly. Again, this is a device that is intended for fixing a rod ("This invention relates generally to a polyaxial screw and coupling apparatus for use with orthopedic fixation systems", Col. 1, lines 15-16). The threads 176 receive cooperating threading on locking nut 185 to fix rod 190 in position.

Urbanski discloses an apparatus and method for spinal fixation. A series of lateral grooves on the screw head mesh with cooperating grooves on the adapter 54 to fix the device in place. Hex nut 40 tightens the assembly to fix the rod in a desired position.

The afore-described references do not describe a facet replacement device, and are quite opposite in construction and use. The devices all secure the rod in one place. A facet replacement must allow coordinated movement in order to be effective. The devices of the cited references do not allow such movement.

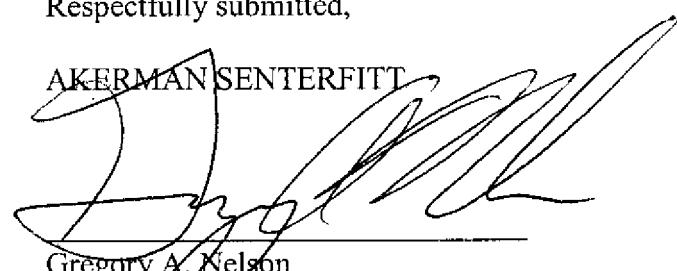
Claim 1 has been amended to describe certain features of the invention that are of particular use in facet replacement. The device includes a rod connecting member with a rod connecting portion and a screw connecting portion. The rod connecting portion is slidably engageable to the rod, and pivotably connected to the screw connecting portion to permit pivoting of the rod connecting portion and the rod about an axis transverse to a long axis of the screw. The screw connecting portion is also slidably engaged to the screw. This construction provides a facet replacement with the desired stability and mobility that is required of a facet joint, and which is unavailable from the references. The device permits sliding of the rod relative to the connecting member. The rod can pivot relative to the screw. Finally, the connecting member can slide relative to the long axis of the screw. The range of features is nowhere shown in the references. In Ulrich, the rod connecting member is a single piece – the rod connecting portion is not pivotal relative to the screw connecting portion. Fournet does not permit vertical movement of the connecting member relative to the screw. Errico and Urbanski similarly angularly fix the rod relative to the screw. One would not be led to combine the references to reach the invention because they all are fixation devices, and there is no intention of providing for mobility.

The invention is an effective solution to the problem of reconstructing and replacing the facet in a manner that permits the required stability and mobility of an effective prosthetic device. The references collectively fail to disclose or suggest to one skilled in the art such a device. Applicant requests reconsideration and allowance of Applicant's pending claims.

This response is accompanied by a Petition for Extension of time, along with authorization to charge the required fee for a three month extension of time, as well as any underpayment in fees, to Deposit Account No. 50-0951.

Respectfully submitted,

~~AKERMAN SENTERFITT~~



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Date: July 20, 2006